

The opinion in support of the decision being entered today was **not** written for publication and is **not** binding precedent of the Board.

Paper No. 18

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte KARL TRYGGVASON, OLAVI LUKKARINEN,
PIRKKO HEIKKILA and TEIJA PARPALA

Appeal No. 2001-2413
Application No. 09/167,894

ON BRIEF

Before FRANKFORT, McQUADE and BAHR, Administrative Patent Judges.
McQUADE, Administrative Patent Judge.

DECISION ON APPEAL

Karl Tryggvason et al. appeal from the final rejection of claims 1 and 7, the only claims pending in the application.

THE INVENTION

The invention relates to "apparatus for delivery of pharmaceuticals to target tissues" (specification, page 1).

Claims 1 and 7 read as follows:¹

¹ In the event of further prosecution, the appellants should consider harmonizing the recitations in claims 1 and 7 of "a means for allowing the conduction of perfusate" and "a means to allow the conduction of perfusate" since it is apparent, when read in light of the underlying disclosure, that these

1. A perfusion apparatus for the prolonged delivery of gene therapy pharmaceuticals in a perfusate to target tissues comprising a means for allowing the conduction of perfusate, a reservoir for the perfusate, a means for propelling the perfusate, a means for oxygenating the perfusate, and suitable means for connecting the apparatus to the target wherein the reservoir, means for propelling the perfusate, means for oxygenating the perfusate and target organ are serially connected by a means to allow the conduction of perfusate.

7. A perfusion system for the delivery of pharmaceuticals in a perfusate to target tissues, said system comprising a perfusate solution containing gene therapy pharmaceuticals wherein said perfusate solution is maintained at a temperature of about 37°C, a means for allowing the conduction of perfusate, a reservoir for the perfusate, a means for propelling the perfusate, a means for oxygenating the perfusate, and suitable means for connecting the apparatus to a target tissue wherein the reservoir, means for propelling the perfusate, means for oxygenating the perfusate and target tissue are serially connected by a means to allow the conduction of perfusate.

THE PRIOR ART

The reference relied on by the examiner to support the final rejection is:

Sadri	5,338,662	August 16, 1994
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THE REJECTIONS

Claim 1 stands rejected under 35 U.S.C. § 102(e) as being anticipated by Sadri.

limitations refer to the same structure.

Appeal No. 2001-2413
Application No. 09/167,894

Claim 7 stands rejected under 35 U.S.C. § 102(e) as being anticipated by Sadri, and under 35 U.S.C. § 103(a) as being obvious over Sadri.

Attention is directed to the appellants' main and reply briefs (Paper Nos. 14 and 16) and to the examiner's answer (Paper No. 15) for the respective positions of the appellants and the examiner with regard to the merits of these rejections.²

DISCUSSION

Sadri discloses a device for perfusing animal organs such as "hearts, kidneys, livers, thyroids, lungs, intestines, pancreases, reproductive organs, brains, spleens and the like" (column 4, lines 52 through 54). The device includes a plurality of reservoirs 1 having a common flow-regulating valve 3, an oxygenator 6, a heat exchanger 8, pumps 12 and 17, and various fluid conduits for conducting the perfusate and connecting the foregoing components in series with the target organ 15. The heat exchanger serves to cool or warm the perfusate (see column

² In the final rejection (Paper No. 7), the examiner also rejected claim 1 under 35 U.S.C. § 103(a) as being obvious over Sadri. As this rejection has not been restated in the answer, we assume it has been withdrawn (see Ex parte Emm, 118 USPQ 180, 181 (Bd. App. 1957)).

6, lines 35 through 47) which can embody a nutrient solution or a therapeutic drug (see columns 1 and 2, and column 5, lines 11 through 26).

The appellants' position that the examiner's rejections are unsound rests on the contention (see pages 4 and 5 in the main brief and pages 1 and 2 in the reply brief) that Sadri does not respond to the limitations in the claims relating to "gene therapy pharmaceuticals." This line of argument is persuasive with respect to claim 7, but not with respect to claim 1.

Turning first to claim 1, anticipation is established when a single prior art reference discloses, expressly or under principles of inherency, each and every element of a claimed invention. RCA Corp. v. Applied Digital Data Sys., Inc., 730 F.2d 1440, 1444, 221 USPQ 385, 388 (Fed. Cir. 1984). It is not necessary that the reference teach what the subject application teaches, but only that the claim read on something disclosed in the reference, i.e., that all of the limitations in the claim be found in or fully met by the reference. Kalman v. Kimberly Clark Corp., 713 F.2d 760, 772, 218 USPQ 781, 789 (Fed. Cir. 1983), cert. denied, 465 U.S. 1026 (1984).

The examiner's analysis as to how each and every structural element set forth in claim 1 is met by Sadri (see pages 3 and 4

Appeal No. 2001-2413
Application No. 09/167,894

in the answer) is reasonable on its face, and has not been specifically challenged by the appellants. The only recitation in the claim pertaining to gene therapy pharmaceuticals appears in the preamble where it merely defines the intended use of the claimed apparatus ("A perfusion apparatus for the prolonged delivery of gene therapy pharmaceuticals in a perfusate to target tissues"). It is not apparent, nor have the appellants pointed out, why the apparatus disclosed by Sadri is not inherently capable of the prolonged delivery of gene therapy pharmaceuticals in a perfusate to target tissues. Moreover, it is well settled that the recitation of an intended use of an old product, even if such use is new, does not make a claim to that old product patentable. See In re Schreiber, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997). In other words, the manner or method in which a machine is to be utilized is not germane to the issue of patentability of the machine itself. In re Casey, 370 F.2d 576, 580, 152 USPQ 235, 238 (CCPA 1967). Hence, the "gene therapy pharmaceuticals" language in claim 1 fails to distinguish the apparatus recited therein over that disclosed by Sadri.

Accordingly, we shall sustain the standing 35 U.S.C. § 102(e) rejection of claim 1 as being anticipated by Sadri.

Appeal No. 2001-2413
Application No. 09/167,894

We shall not sustain, however, the standing 35 U.S.C. § 102(e) rejection of claim 7 as being anticipated by Sadri.

In contrast to claim 1, claim 7 recites as a positive element of the claimed perfusion system a "perfusate solution containing gene therapy pharmaceuticals . . . maintained at a temperature of about 37°C." Sadri does not disclose a perfusion system including such a solution. As the solution is a required element of the claimed subject matter, the examiner's determination (see page 3 in the answer) that the Sadri apparatus, by virtue of its heat exchanger, is inherently capable of maintaining a perfusate solution at a temperature of about 37°C is of no moment.

We also shall not sustain the standing 35 U.S.C. § 103(a) rejection of claim 7 as being obvious over Sadri.

Allowing that Sadri may not teach a "perfusate solution containing gene therapy pharmaceuticals . . . maintained at a temperature of about 37°C," the examiner concludes (see pages 4 through 6 in the answer) that the use of same in the Sadri apparatus would have been an obvious substitution of one therapeutic solution for another. As indicated above, Sadri does not in fact teach the solution in question, and notwithstanding the discussion therein of various other perfusates, it does not

Appeal No. 2001-2413
Application No. 09/167,894

provide the factual basis necessary to support the examiner's conclusion.

Upon the return of the application to the technology center, the examiner may wish to consider whether the above noted deficiency in Sadri relative to the subject matter recited in claim 7 might be cured by prior art gene therapy techniques, such as those exemplified by U.S. Patent No. 5,328,470 to Nabel et al., which is of record, and/or International Application No. WO 93/09239, a copy of which is attached, thereby warranting the entry of a new 35 U.S.C. § 103(a) rejection of this claim.

SUMMARY

The decision of the examiner to reject claims 1 and 7 is affirmed with respect to claim 1 and reversed with respect to claim 7.

Appeal No. 2001-2413
Application No. 09/167,894

No period for taking any subsequent action in connection
with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED-IN-PART

CHARLES E. FRANKFORT)	
Administrative Patent Judge)	
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)	BOARD OF PATENT
JOHN P. McQUADE)	APPEALS
Administrative Patent Judge)	AND
)	INTERFERENCES
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JENNIFER D. BAHR)	
Administrative Patent Judge)	

JPM/gjh

Appeal No. 2001-2413
Application No. 09/167,894

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